II. FY02: BPD Reports Submitted By Blood And Plasma Establishments:

Total BPDs By Manufacturing System

MANUFACTURING SYSTEM	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
POST DONATION INFORMATION	16513	2291	0	4358	23162	69.2%
QC & DISTRIBUTION	2164	1064	517	130	3875	11.6%
LABELING	948	986	412	21	2367	7.1%
DONOR SCREENING	1309	186	0	537	2032	6.1%
ROUTINE TESTING	259	407	363	10	1039	3.1%
COMPONENT PREPARATION	266	146	12	0	424	1.3%
BLOOD COLLECTION	160	31	0	16	207	0.6%
MISCELLANEOUS	137	2	0	22	161	0.5%
DONOR DEFERRAL	48	6	0	64	118	0.4%
VIRAL TESTING	48	23	0	10	81	0.2%
TOTAL	*21852*	*5142*	*1304*	*5168*	*33466*	*100.0%*

***Potential* Recalls By Manufacturing System**

MANUFACTURING SYSTEM	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
DONOR SCREENING	720	47	0	352	1119	51.5%
QC & DISTRIBUTION	259	17	2	95	373	17.2%
COMPONENT PREPARATION	159	62	0	0	221	10.2%
BLOOD COLLECTION	97	8	0	13	118	5.4%
LABELING	101	11	0	3	115	5.3%
DONOR DEFERRAL	40	3	0	49	92	4.2%
POST DONATION INFORMATION	57	0	0	10	67	3.1%
VIRAL TESTING	33	7	0	8	48	2.2%
ROUTINE TESTING	15	2	0	3	20	0.9%
TOTAL	*1481*	*157*	*2*	*533*	*2173*	*100.0%*

For blood and plasma, post donation information (PDI) continues to be the most frequently reported event. The most common PDI involved donors providing information concerning travel to malarial endemic areas and travel to an area at potential risk for vCJD.

FY02 Post Donation Information (PDI) - How Obtained

PDI OBTAINED THROUGH:	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	PLASMA CENTERS	TOTAL	
SUBSEQUENT DONATION	15,235	1910	3824	20,969	90.5%
TELEPHONE CALL FROM DONOR	936	331	18	1285	5.5%
THIRD PARTY (e.g., doctor, family)	342	50	516	908	3.9%
TOTAL	16,513	2291	4358	23,162	100%

THE PDI WAS:	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	PLASMA CENTERS	TOTAL	
KNOWN, BUT NOT PROVIDED AT TIME OF DONATION*	14,729	1823	4000	20,552	88.7%
NOT KNOWN AT TIME OF DONATION**	1784	468	358	2610	11.3%
TOTAL	16,513	2291	4358	23,162	100%

* known, e.g., travel outside of U.S., tattoo or body piercing, history of cancer

**not known, e.g., post donation illness, cancer diagnosed post donation, sex partner participated in high risk behavior or tested positive

Most Frequent Types of Post Donation Information (PDI) From Licensed Blood Establishments

POST DONATION INFORMATION (PDI) *16513 (75.6%)*	# Reports	% of Total PDI
Behavior/History	***14731***	***89.2%***
Travel to malaria endemic area/history of malaria	4086	24.7%
Risk factors associated with Creutzfeldt-Jakob Disease (CJD) – travel	3600	21.8 %
History of cancer	790	4.8%
Donor received tattoo within 12 months of donation	616	3.7%
History of disease	536	3.2%
Received medication or antibiotics	440	2.7%
IV drug use	418	2.5%
Received Proscar, Tegison or Accutane	400	2.4%
Male donor had sex with another man	392	2.4%
Sex partner tested positive for HCV	308	1.9%
Donor received bone graft or transplant	303	1.8%
Illness	***1478***	***9.0%***
Post donation illness (not hepatitis, HIV, HTLV-I, STD, or cold/flu related)	845	5.1%
Post donation diagnosis of cancer	590	3.6%
Testing *	***212***	***1.3%***
Not specifically related to high risk behavior	***91***	***0.6%***
Donated to be tested or called back for test results	50	0.3%
Donor does not want their blood used	30	0.2%

*****Includes: tested positive for viral marker either prior to or post donation

Most Frequent Types of Quality Control & Distribution BPDs From Licensed Blood Establishments

QC & DISTRIBUTION *2164 (9.9%)*	# Reports	% of Total QC & Distribution
Unsuitable product	***1384***	***64.0%***
Unit or segments contained clots or would not flow through filter	904	41.8%
Unit or segment hemolyzed	412	19.0%
Inappropriate release of:	***372***	***17.2%***
Product in which instrument QC or validation was unacceptable or not documented	72	3.3%
Product released prior to resolution of discrepancy	62	2.9%
Outdated product	33	1.5%
Product identified as unsuitable due to donor screening procedures not followed	32	1.5%
Shipping and storage	***173***	***8.0%***
Shipped at incorrect temperature	127	5.9%
Stored at incorrect temperature	37	1.7%
Failure to quarantine unit due to medical history:	***48***	***2.2%***
Post donation illness	10	0.5%
Improper blood bank practices	***119***	***5.5%***
Failure to quarantine unit due to incorrect, incomplete, or positive testing	***43***	***2.0%***
Failure to quarantine unit due to testing not performed or documented	***25***	***1.2%***

Most Frequent Types of Donor Screening BPDs From Licensed Blood Establishments

DONOR SCREENING *1308 (6.0%)*	# Reports	% of Total Donor Screening
Donor gave history which warranted deferral and was not deferred	***614***	***46.9%***
Travel to malaria endemic area/history of malaria	293	22.4%
Received medication or antibiotics	67	5.1%
History of cancer	61	4.7%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel	39	3.0%
History of disease	32	2.4%
Donor record incomplete, incorrect, or not reviewed	***389***	***29.7%***
Donor history questions	318	24.3%
Arm inspection	29	2.2%
Incorrect ID used during deferral search	***162***	***12.4%***
Donor not previously deferred	*135*	*10.3%*
Donor previously deferred due to testing	*14*	*1.1%*
Donor did not meet acceptance criteria	***102***	***7.8%***
Hemoglobin or Hematocrit unacceptable or not documented	49	3.7%
Temperature unacceptable or not documented	42	3.2%
Deferral screening not done	***41***	***3.1%***

Most Frequent Types of Labeling BPDs From Licensed Blood Establishments

LABELING *948 (4.3%)*	#Reports	% of Total Labeling
Crossmatch tag or tie tag labels incorrect or missing information	***466***	***49.2%***
Recipient identification missing or incorrect	297	31.3%
Autologous unit	201	21.2%
Unit or pool number incorrect or missing	22	2.3%
Antigen incorrect or missing	21	2.2%
Irradiation status incorrect or missing	20	2.1%
Blood unit labels	***438***	***46.2%***
Extended expiration date or time	105	11.1%
Product type incorrect	72	7.6%
Volume incorrect or missing	70	7.4%
ABO and/or Rh incorrect	64	6.8%
Transfusion record (crossmatch slip) incorrect or missing information	***44***	***4.6%***
Recipient identification missing or incorrect	28	3.0%

Most Frequent Types of Post Donation Information (PDI) From Unlicensed Blood Establishments

POST DONATION INFORMATION (PDI) *2291 (44.6%)*	# Reports	% of Total PDI
Behavior/History	***1871***	***81.7%***
Travel to malaria endemic area/history of malaria	948	41.4%
Risk factors associated with Creutzfeldt-Jakob Disease (CJD) - travel	317	13.8%
History of cancer	67	2.9%
Donor received medication or antibiotics	57	2.5%
Sex partner engaged in high risk behavior	53	2.3%
Illness	***13***	***10.3%***
Post donation diagnosis of cancer	240	10.5%
Post donation illness (not hepatitis, HIV, HTLV-I, STD, or cold/flu related)	158	6.9%
Testing	***9***	***0.4%***

Most Frequent Types of Quality Control & Distribution BPDs From Unlicensed Blood Establishments

QC & Distribution *1064 (20.7%)*	# Reports	% of Total QC & Distribution
Improper blood bank practices	***629***	***59.1%***
Product not irradiated as required	182	17.1%
Improper ABO or Rh type selected for patient	85	8.0%
Improper product selected for patient	59	5.5%
Unit released prior to obtaining current sample for ABO, Rh, antibody screen and/or crossmatch testing	56	5.3%
Unit issued from the blood bank to wrong patient	54	5.1%
Unsuitable product	***125***	***11.7%***
Unit or segments contained clots or would not flow through filter	71	6.7%
Unit or segment hemolyzed	32	3.0%
Failure to quarantine unit due to testing not performed or documented for:	***115***	***10.8%***
Antigen screen	33	3.1%
Crossmatch	30	2.8%
Antibody screen or identification	29	2.7%
Inappropriate release of:	***112***	***10.5%***
Outdated product	61	5.7%
Product with unacceptable or undocumented product QC	18	1.7%
Product in which instrument QC or validation unacceptable or not documented	6	0.6%
Product identified as unsuitable due to component preparation procedures not followed	6	0.6%
Failure to quarantine due to incorrect, incomplete, or positive testing:	***36***	***3.4%***
Antibody screen or identification	16	1.5%
Shipping and storage	***31***	***2.9%***
Stored at incorrect temperature	16	1.5%
Shipped at incorrect temperature	14	1.3%

Most Frequent Types of Labeling BPDs From Unlicensed Blood Establishments

LABELING *986 (19.1%)*	# Reports	% of Total Labeling
Crossmatch tag or tie tag labels incorrect or missing information	***441***	***44.7%***
Recipient identification incorrect or missing	123	12.5%
Unit or pool number incorrect or missing	64	6.5%
Crossmatch tag switched, both units intended for the same patient	62	6.3%
Irradiation status incorrect or missing	31	3.1%
Blood unit labels	***340***	***34.5%***
Extended expiration date or time	155	15.7%
ABO and/or Rh incorrect	45	4.6%
Donor number incorrect or missing	43	4.4%
Product type incorrect	39	4.0%
Transfusion record (crossmatch slip) incorrect or missing information	***205***	***20.8%***
Recipient identification incorrect or missing	50	5.1%
Transfusion record switched, both units intended for the same patient	38	3.9%
Unit or pool number incorrect or missing	33	3.3%

Most Frequent Types of Routine Testing BPDs From Unlicensed Blood Establishments

ROUTINE TESTING *407 (7.9%)*	# Reports	% of Total Routine Testing
Incorrectly tested for:	***245***	***60.2%***
Antibody screening or identification	77	18.9%
Compatibility	74	18.2%
Rh	37	9.1%
Antigen typing	25	6.1%
ABO	21	5.2%
Sample (used for testing) identification	***141***	***34.6%***
Sample incorrectly or incompletely labeled	98	24.1%
Incorrect sample tested	28	6.9%
Unsuitable sample used for testing (e.g., too old)	15	3.7%
Reagent QC unacceptable or expired reagents used	***21***	***5.2%***
Antibody screening or identification	10	2.5%

Most Frequent Types of Quality Control & Distribution BPDs From Transfusion Services

QC & DISTRIBUTION *517 (39.6%)*	# Reports	% of Total QC & Distribution
Improper blood bank practices	***352***	***68.3%***
Procedure for issuing unit not followed	72	14.0%
Product not irradiated as required	60	11.7%
Unit issued from the blood bank to wrong patient	35	6.8%
Unit released prior to obtaining current sample for ABO, Rh, antibody screen and/or crossmatch testing	35	6.8%
Filter not issued with product or incorrect filter issued	32	6.2%
Improper ABO or Rh type selected for patient	31	6.0%
Product not leukoreduced as required	31	6.0%
Failure to quarantine unit due to testing not performed or documented for:	***82***	***15.9%***
Antigen screen	41	8.0%
Antibody screen	17	3.3%
Crossmatch	10	1.9%
Shipping and/or storage temperature incorrect	***24***	***4.6%***
Inappropriate release of:	***42***	***8.1%***
Outdated product	33	7.0%
Failure to quarantine unit due to incorrect, incomplete, or positive testing for:	***9***	***1.7%***
Antigen screen	4	0.8%

Most Frequent Types of Labeling BPDs From Transfusion Services

LABELING *412 (31.6%)*	# Reports	% of Total Labeling
Crossmatch tag or tie tag labels incorrect or missing information	***239***	***58.0%***
Recipient identification incorrect or missing	74	18.0%
Unit or pool number incorrect or missing	46	11.2%
Crossmatch tag switched, both units intended for the same patient	39	9.5%
Expiration date or time extended or missing	12	2.9%
Leukoreduced status incorrect or missing	12	2.9%
Transfusion record (crossmatch slip) incorrect or missing information	***96***	***24.3%***
Recipient identification incorrect or missing	36	8.7%
Unit or pool number incorrect or missing	17	4.1%
Transfusion record switched, both units intended for the same patient	9	2.2%
Blood unit labels	***77***	***18.7%***
Expiration date or time extended or missing	41	10.0%
ABO and/or Rh incorrect	10	2.4%
Donor number incorrect or missing	10	2.4%

Most Frequent Types of Routine Testing BPDs From Transfusion Services

ROUTINE TESTING *363 (27.8%)*	# Reports	% of Total Routine Testing
Incorrectly tested for:	***196***	***54.0%***
Antibody screening or identification	74	20.4%
Compatibility	53	14.6%
ABO	22	6.1%
Rh	20	5.5%
Sample (used for testing) identification	***137***	***37.7%***
Sample incorrectly or incompletely labeled	102	28.1%
Incorrect sample tested	23	6.3%
Reagent QC unacceptable or expired reagents used	***30***	***8.3%***
Antibody screening or identification	9	2.5%
Antigen typing	8	2.2%
ABO	7	1.9%

Most Frequent Types of Post Donation Information (PDI) From Plasma Centers

POST DONATION INFORMATION (PDI) *4358 (84.3%)*	# Reports	% of Total PDI
Behavior/History	***4166***	***95.6%***
Donor received tattoo within 12 months of donation	1555	35.7%
Donor received body piercing within 12 months of donation	581	13.3%
Incarcerated	435	10.0%
Donor received ear piercing within 12 months of donation	204	4.7%
Non-IV-drug use	162	3.7%
Sex partner tested positive for HCV	160	3.7%
IV drug use	128	2.9%
Testing*	***169***	***3.9%***
Tested positive at another center, specific testing unknown	122	2.4%

*Includes testing positive for viral marker prior to or post donation

Most Frequent Types of Donor Screening BPDs Received From Plasma Centers

DONOR SCREENING *537 (10.4%)*	# Reports	% of Total Donor Screening
Donor record incomplete, incorrect, or not reviewed	***241***	***44.9%***
Donor history questions	150	27.9%
Arm inspection	75	14.0%
Donor identification	7	1.3%
Donor did not meet acceptance criteria	***148***	***27.6%***
Temperature unacceptable or not documented	57	10.6%
Medical review or physical not performed or inadequate	53	9.9%
Other	15	2.8%
Deferral screening not done	***84***	***15.6%***
Donor previously deferred due to history	***62***	***11.5%***
Non-IV drug use	8	1.5%
History of disease or surgery	8	1.5%
Incarcerated	8	1.5%
IV drug use	6	1.1%
Deferred by another center	6	1.1%
Donor gave history which warranted deferral and was not deferred	***29***	***9.9%***
Donor received tattoo within 12 months of donation	19	3.5%
Donor received body piercing within 12 months of donation	8	1.5%
Non-IV-drug use	5	0.9%
Donor previously deferred due to testing:	***19***	***3.5%***
Elevated for ALT	10	1.9%
Incorrect ID used during deferral search	***11***	***2.0%***
Donor previously deferred due to history	***7***	***1.3%***
Donor previously deferred due to testing	***3***	***0.6%***

BLOOD AND PLASMA ESTABLISHMENTS

Timeliness Of BPDs

Number of Days From Date Discovered To Date FDA Received

CUMULATIVE % OF REPORTS	Licensed (Days)	Unlicensed (Days)	Transfusion Service (Days)	Plasma (Days)	Total (Days)
10%	14	10	4	24	14
25%	21	24	12	35	22
50%	28	41	27	46	30
75%	34	112	43	81	43
90%	49	193	52	130	89
# REPORTS	21849	5137	1304	5162	33452
RANGE	0-1551	0-551	0-441	0-1473	0-1551
AVERAGE	36	75	32	70	47
# Reports lacking date discovered	*3*	*5*	*0*	*6*	*14*

Adherence To 45 Day Required Timeframe For Reporting

(Reporting Time = Date of FDA receipt – Date of discovery of BPD)

Reporting Time (days)	Licensed Establishments		Unlicensed Establishments		Transfusion Services		Plasma Centers		Total	
< or = 45	**19141**	**87.6%**	**2810**	**54.7%**	**1047**	**80.3%**	**2480**	**48.1%**	**25478**	**76.2%**
Between 45 and 90	2004	9.2%	849	16.5%	226	17.3%	1582	30.6%	4661	13.9%
> 90	704	3.2%	1478	28.8%	31	2.4%	1100	21.3%	3313	9.9%
Total	21849	100.0%	5137	100.0%	1304	100.0%	5162	100.0%	33452	100.0%
*Reporting time=0	3		40		20		1		64	

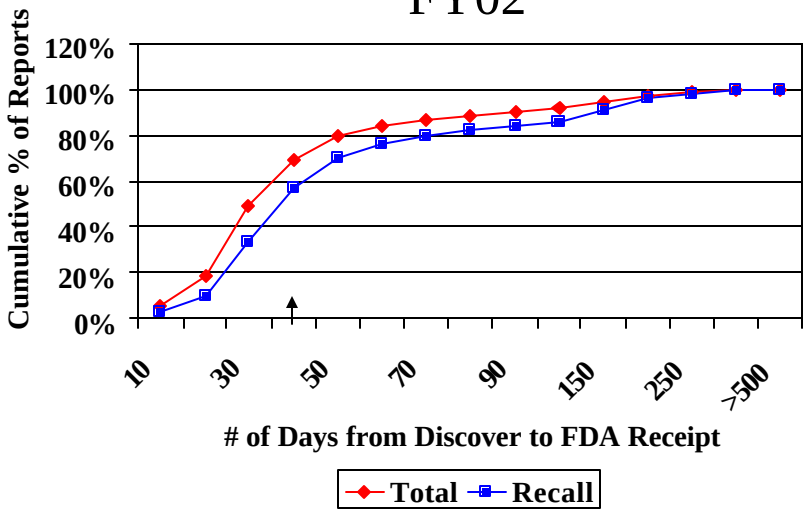
*Reporting time = 0 - reports were submitted electronically on the day discovered.

Biological Product Deviation Reports

Blood and Plasma Establishments

Reporting Time

FY02



Total Reports = 33,466

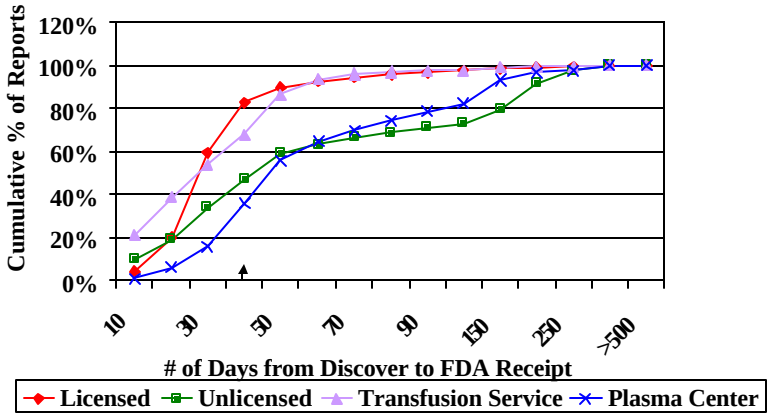
Potential Recalls = 2191

Biological Product Deviation Reports

Blood and Plasma Establishments

Reporting Time – Total Reports

FY02



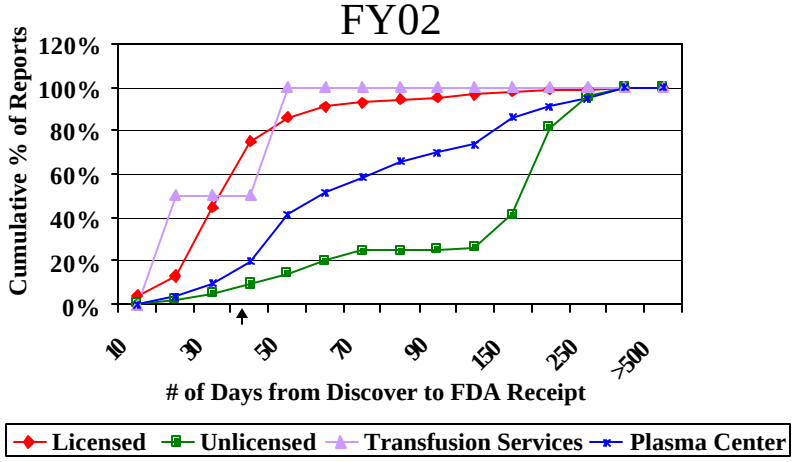
Total Reports = 33,466
Licensed Blood Est. = 21,852; Unlicensed Blood Est. = 5142; Transfusion Services = 1304; Plasma Centers = 5168

Biological Product Deviation Reports

Blood and Plasma Establishments

Reporting Time – Potential Recalls

FY02



Total Reports = 2191
Licensed Blood Est. = 1481; Unlicensed Blood Est. = 157; Transfusion Services = 2; Plasma Centers = 242